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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,902	03/09/2004	Jun Li	11287.105001 AST100	1631
20786	7590	09/17/2008		
KING & SPALDING LLP 1180 PEACHTREE STREET ATLANTA, GA 30309-3521			EXAMINER FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1618	
			MAIL DATE	DELIVERY MODE
			09/17/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/796,902

**Applicant(s)**

LI ET AL.

**Examiner**

BLESSING M. FUBARA

**Art Unit**

1618

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21, 23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) 19, 20, 23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

### **DETAILED ACTION**

Examiner acknowledges receipt of amendment and remarks filed 6/17/08. Claim 22 is canceled. Claim 1 is amended. Claims 1-21, 23 and 24 are pending.

### ***Response to Arguments***

Previous rejections that are not reiterated herein are withdrawn.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 10-13, 17, 18 and 21 remain rejected under 35 U.S.C. 102(b) as being anticipated by Fick (US 5,945,100) or Lu et al. ("Cell Encapsulation with Alginate and  $\omega$ -Phenoxycinnamylidene-Acetylated Poly(allylamine)," in Biotechnol. Bioeng., 2000, 70 (5), pp. 479-483 for reasons of record and reiterated herein below.
3. Fick discloses tumor delivery vehicle that can be made of natural polymers (column 8), synthetic polymers that are cross-linkable by hydrogen bonding (column 10, line 45 to column 11, line 10); Fick contemplates the use of water soluble polymers that include cinnamoyl groups that may be photochemically cross-linked (column 11, lines 22-25). These polymers are used for encapsulating bioactive agents with the polymers forming semipermeable membrane around the encapsulated materials (column 12, lines 64, 65; column 8, lines 51-54). Fick meets the requirements of the claims in terms of microcapsule, semipermeable membrane, the presence of cinnamoyl groups on the membrane and in terms of the bioactive agent.

***Response to Arguments***

4. Applicant's arguments filed 6/17/08 have been fully considered but they are not persuasive.
5. Applicant argues that column 12, lines 64 and 65 does not teach the formation of microcapsules from the polymers comprising plurality of cinnamoyl groups and applicant does argues that Fick does not teach all the limitations of the claims. The examiner disagrees. Claim 1 is a microcapsule and Fick contemplates microcapsule (column 8, lines 49, 51,54); and Fick contemplates the use of water soluble polymers that include cinnamoyl groups that may be photochemically cross-linked (column 11, lines 22-25).
6. Lu discloses microcapsules that comprise semipermeable polymer membrane that is used to encapsulate cells; the polymer comprises alginate and two types of photosensitive polyallylamine that are modified by  $\alpha$ -phenoxycinnamylidene acetyl chloride (abstract). Lu thus meets the requirement of the claims in times of the semipermeable microcapsule, cells as bioactive agents, and the presence of cinnamoyl groups in the membrane.

***Response to Arguments***

7. Applicant's arguments filed 6/17/08 have been fully considered but they are not persuasive.
8. Applicant argues that Lu does not teach all the limitations of the claims because Lu uses radiations at wavelength of 300-325 nm to cross link the cinnamoyl groups and that the Lu process results in damage to bioactive agents. The examiner disagrees because claim 1 says that the exposure of the cinnamoyl groups to radiation causes "minimal," reduced" or "no damage."

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In this wise it is noted that the claims have not recited the wavelength of radiation to which the cinnamoyl groups are exposed, minimal or reduced are relative terms and does not all damage to bioactive agents, bioactive substance is very broad and encompasses many bioactive agents that may not be sensitive, further, applicant does not give examples of bioactive agents that are damaged by 300-325 nm radiation that are encapsulated in the Lu reference; also, Lu does not say that the bioactive agent incorporated within the capsule are damaged; and “when the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

*Claim Rejections - 35 USC § 103*

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-18 and 21 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lu et al. ("Cell Encapsulation with Alginate and  $\omega$ -Phenoxycinnamylidene-Acetylated Poly(allylamine)," in *Biotechnol. Bioeng.*, 2000, 70 (5), pp. 479-483) in view of Chia et al. ("Hepatocyte Encapsulation for enhanced Cellular Functions," in *Tissue Engineering*, Vol. 6, no. 5, (2000) pp. 481-495) or Sun et al. ("Microencapsulated Hepatocytes: AN in Vitro and in vivo study," *Biomat. Artif. Cells Art. Org.*, 1987, 15. pp 1483-1496) according to the rejections of record and reiterated herein below.

Claims 1, 2, 10-13, 17 and 18 have been shown above to be anticipated by Lu. Lu teaches microparticles that is comprised of polymer and would flow that that microcapsules have inner and outer layer that are made up of polymer; claim 3 does not distinguish the first and second polymers, and Lu teaches two types of polymers and thus meets claim 3. The electrical charge on the polymer of the microcapsule of claim 4 would be inherent to the microcapsule of Lu. Claims 5-7 are met because the membrane of Lu has cinnamoyl groups. Regarding claims 8 and 9, the specific polymers used can be used in the Lu delivery vehicles. Regarding claim 16, one cinnamoyl compound can be used in place of the other. For claim 14, the artisan has the technical expertise to determine how much cinnamoyl compound can be used to obtain the desired concentration of cinnamoyl groups on the membrane and for claim 15, the specification does not provide unexpected result deriving from the particle size. Claim 18 is a combination of claims 1, 17, 3 and 4 so that claim 18 is inherent and in the absence of factual evidence of unexpected result, the particle size does not patentably distinguish the invention over the prior art. Exposing the cinnamoyl to light at a particular wavelength of 340 nm to 700 nm, which is in the visible region of the spectrum, is a process of carrying out the cross-linking and thus

makes claim 18 a product by process claim. Lu does not disclose the use of the delivery vehicle in a liver assist device. But both Chia and Sun disclose the use of alginate-polyamino acid membrane for encapsulating hepatic cells. Therefore, taking the general teachings of Lu as encapsulating cells, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that the device of LU would effectively encapsulate cells including liver cells.

***Response to Arguments***

12. Applicant's arguments filed 6/17/08 have been fully considered but they are not persuasive.

13. Applicant argues that the amendment to the claims overcomes the rejection. This is not persuasive because the amended claims do not overcome the rejection.

Applicant argues that the amendment to claim 1 specifying that the cinnamoyl groups form cross-links upon exposure to radiation at wavelengths that cause minimal, reduced or no damage to the bioactive substance overcomes the Lu art that exposes the cinnamoyl groups to wavelengths of 300-325 nm, which damages the encapsulated bioactive agents. The examiner disagrees. While page 4, lines 14-17 of the instant specification the cells are damaged when the monomers are subjected to 300-325 nm light, it is noted that Lu does not say that cells encapsulated by the membrane are damaged and minimal or reduced are relative terms, it is also noted that the goal of Lu is to encapsulate cells in order to circumvent the problem of host rejection by immune response, also, Lu does not say that those cells encapsulated are damaged, and applicant has not provided factual showing that the cells encapsulated in Lu are damaged.

No claim is allowed.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

/Blessing M. Fubara/  
Examiner, Art Unit 1618